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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/270,983 03/17/99 HAY

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EXAMINER

LISA A. HAILE, PH.D
GRAY CARY WARE & FREIDENRICH LLP
4365 EXECUTIVE DRIVE,
SUITE 1600
SAN DIEGO CA 92121

HUTSON, R

ART UNIT

PAPER NUMBER

1652

DATE MAILED:

07/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/270,983

Applicant(s)

HAY ET AL.

Examiner

Richard G Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-56 is/are pending in the application.
- 4a) Of the above claim(s) 10-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☒ Claim(s) 4-8 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

Applicants amendment of claim 3 and cancellation of claim 9 is acknowledged.

Claims 1-8 and 10-56 are still at issue and are present for examination.

Applicants' arguments filed on 4/9/2001, paper No. 10, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claims 10-56 remain withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Objections

Claims 4-8 are objected to because of the following informalities: Claims 4-8 depend from rejected claims 1 and 3. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, and 3 and are rejected under 35 U.S.C. 102(e) as being anticipated by Tsien et al. (U.S. Patent No. 5,981,200).

The rejection is stated in the previous office action as it applied to claims 1, 2, 3, and 9.

Applicants traverse this rejection on the following basis. Applicants assert that Tsien et al. teaches a tandem fluorescent protein construct comprising a donor

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fluorescent protein moiety, an acceptor fluorescent moiety, and a peptide linker that couples the donor and acceptor fluorescent protein moieties. Applicants assert that Tsien et al. teaches only fluorescent protein moiety constructs that transfer fluorescence energy, and that Tsien et al. does not teach or suggest using a protein construct containing a repressor protein and a reporter protein. Applicants further assert that Tsien et al. does not teach or suggest using any protein moiety other than fluorescent protein moieties. Therefore, Tsien et al. does not anticipate applicants invention. This argument is not found persuasive on the basis of applicants original disclosure of what applicants invention encompasses. Specifically, applicants submission of what is encompassed by a fusion protein comprising a reporter polypeptide linked to a linker polypeptide comprising a protease cleavage site and a repressor polypeptide that represses the activity of said reporter polypeptide, wherein said repressor is operatively linked to the linker polypeptide does not support applicants above argument. On page 10, lines 21-24 of the specification, applicants recite "Two proteins, wherein a fluorescence energy transfer occurs between the two proteins can also be used as a reporter polypeptide. In one embodiment, the two proteins are linked by a protease cleavage site, such that a different emission spectra is seen when the two fluorescent polypeptides are attached and when they are separated. Further, claim 9, now cancelled by applicants further supports such a broad interpretation of the claimed invention, specifically claim 9 recites "the fusion protein of claim 1, wherein said reporter polypeptide and said repressor polypeptide are fluorescent polypeptides and wherein fluorescence energy transfer occurs between said reporter polypeptide and said

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repressor polypeptide, wherein cleavage at said protease cleavage sites results in an alteration in fluorescence energy transfer between said reporter polypeptide and said repressor polypeptide." This admission by applicants of what is encompassed by the claimed invention is anticipated by Tsien et al.

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Knight. (Methods in Enzymology 248: 18-34, 1995).

The rejection is stated in the previous office action as it applied to claims 1, 3 and 9.

Applicants traverse this rejection as the above rejection on the basis that while Knight et al. teach the construction of fusion proteins comprising fluorescent proteins and a peptide linker, Knight et al. does not teach or suggest using non-fluorescent protein moiety constructs and therefore Knight et al. does not anticipate applicants invention. As above, this argument is not found persuasive on the basis of applicants original disclosure of what applicants invention encompasses. Specifically, applicants submission that a fusion protein comprising a reporter polypeptide linked to a linker polypeptide comprising a protease cleavage site and a repressor polypeptide that represses the activity of said reporter polypeptide encompasses two proteins, wherein a fluorescence energy transfer occurs between the two (See above discussion of Tsien et al. rejection).

Of interest are Dasmahapatra (U.S. Patent No. 5,599,906) and Germann et al. (U.S. Patent No. 6,117,639) drawn to protein constructs and methods of their use in protease assays.

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Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapy Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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Richard Hutson Ph.D.
June 28, 2001



REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP 1600
1600